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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,248	03/26/2001	Peter Baumann	89491/201	8759
30542	7590	08/26/2003		
FOLEY & LARDNER P.O. BOX 80278 SAN DIEGO, CA 92138-0278			EXAMINER	
			MYERS, CARLA J	
		ART UNIT	PAPER NUMBER	
		1634		

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/816,248	BAUMANN ET AL.
	Examiner Carla Myers	Art Unit 1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extended time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 06 June 2003.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 37-48 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 38,39,42 and 43 is/are allowed.  
 6) Claim(s) 37,40,41 and 44-48 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.      4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 6, 2003 has been entered.

Claims 37-48 are pending. All rejections not reiterated herein are hereby withdrawn. This action contains new grounds of rejection and is made non-final.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37, 40, 41, 44-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated human Pot-1 polypeptides comprising SEQ ID NO: 13, 15 and 17, isolated Pot-1 polypeptides encoded by the polynucleotides of SEQ ID NO: 12, 14 or 16, and polypeptides consisting of SEQ ID NO: 5, does not reasonably provide enablement for polypeptides having 85% identity with SEQ ID NO: 13, 15 or 17 or with polypeptides encoded by SEQ ID NO: 12, 14 or 16, or encoded by polynucleotides which hybridize under high stringency conditions to

SEQ ID NO: 12, or fragments of said polypeptides which bind single-stranded telomeric DNA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors have been considered in formulating this rejection (*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

The claims are drawn to polypeptides having 85% identity to SEQ ID NO: 13,1 5 or 17 and polypeptides encoded by a polynucleotide that hybridizes to SEQ ID NO: 12 under high stringency conditions, wherein said polypeptide is not the amino acid sequence set forth in SEQ ID NO: 13 and said polypeptide binds single-stranded telomeric DNA. The claims further include fragments of said polypeptides which bind to single-stranded telomeric DNA. The claims as broadly written include splice variants, homologs, allelic variants and naturally-occurring and non-naturally occurring mutants of the polypeptides of SEQ ID NO: 13, 15 and 17. The teachings in the specification are not commensurate in scope with the invention as it is broadly claimed for the following reasons:

The specification teaches 2 splice variants of the human Pot1 protein, wherein said variants consist of SEQ ID NO: 15 and 17. The claims have been amended to

specifically exclude polypeptides having the amino acid sequence of SEQ ID NO: 13. Accordingly, the specification has taught only 2 species which fall within the claimed genus of any polypeptide having 85% identity with SEQ ID NO: 13, 15 or 17. Two members within the broadly claimed genus does not constitute a representative number of members within this genus. The specification does not disclose any additional splice variants and does not disclose any other types of variants of the human Pot1 protein. The specification does not teach any non-human Pot-1 polypeptides, as is encompassed by the claims directed to fragments and fragments comprising SEQ ID NO: 5. Nor does the specification teach any mutant or polymorphic variants of Pot-1. The modification of a polypeptide by even a single amino acid may alter the functional activity of the encoded polypeptide. In the instant application, there are no teachings in the specification as to which amino acids within SEQ ID NO: 13, 15 or 17 can be modified without altering the ability of the polypeptide to bind to single-stranded telomeric DNA. While one could envision a substitution, deletion or addition of an amino acid at each position of SEQ ID NO: 13, 15 and 17 and one could possibly assay these polypeptides to determine whether such modifications alone or together with other undefined modifications alter the ability of the polypeptide to bind to single-stranded telomeric DNA, such random experimentation is considered to be undue. It is highly unpredictable as to which amino acids within SEQ ID NO: 13, 15 or 17 could be modified and which amino acids could be added or deleted without altering the ability of the encoded polypeptide to bind to single-stranded telomeric DNA. Knowledge of the wild-type sequence and of 2 splice variants of human Pot-1 does not lead one to

specific homologs, allelic, mutant and splice variants of Pot-1 which have the ability to bind to single-stranded telomeric DNA.

Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art. Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". In the instant application, the scope of the claims does not bear a reasonable correlation to the scope of enablement because the specification has not disclosed a representative number of hPot-1 polypeptides within the broadly claimed genus. Further, the art of modifying polypeptides by introducing amino acid substitutions, deletions and additions into the polypeptide is highly unpredictable and the specification has not provided specific guidance as to how the polypeptides of SEQ ID NO: 13, 15 and 17 can be modified without altering their ability to bind to single-stranded telomeric DNA. Accordingly, undue experimentation would be required to practice the invention as it is broadly claimed.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37, 40, 41, 44, 45-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Isogai (NCBI Database, Accession NO. BAA91988, February 22, 2000).

Isogai teaches a human protein product which differs from SEQ ID NO: 13 in that it contains an aspartate at amino acid position 410 in place of a valine. In the absence of evidence to the contrary, given the extensive sequence identity between the protein of Isogai and the protein of SEQ ID NO: 13 (i.e., 99% identity), it is considered to be an inherent property of the protein of Isogai that it binds single-stranded telomeric DNA. It is noted that the protein product set forth by Isogai has the same chemical structure (i.e., amino acid sequence) as the polypeptide presently encompassed by the claims. A chemical composition and its properties are inseparable. The claims do not recite any structural limitations which would distinguish the presently claimed polypeptides over the protein product of Isogai. With respect to claims 47 and 48, the protein of Isogai is considered to be a fragment of the undefined/unspecified polypeptide of claim 37. With respect to claim 46, the protein of Isogai is considered to be a splice variant of the undefined/unspecified polypeptide of claim 37.

4. Claims 37, 40, 41, 44, 45-48 are rejected under 35 U.S.C. 102(a) as being anticipated by Isogai (NCBI Database, Accession NO. BAB14110, September 29, 2000).

Isogai teaches a human protein product which differs from SEQ ID NO: 13 in that it contains an aspartate at amino acid position 410 in place of a valine. In the absence of evidence to the contrary, given the extensive sequence identity between the protein of Isogai and the protein of SEQ ID NO: 13 (i.e., 99% identity), it is considered to be an inherent property of the protein of Isogai that it binds single-stranded telomeric DNA. It is noted that the protein product set forth by Isogai has the same chemical structure (i.e., amino acid sequence) as the polypeptide presently encompassed by the claims. A chemical composition and its properties are inseparable. The claims do not recite any structural limitations which would distinguish the presently claimed polypeptides over the protein product of Isogai. With respect to claims 47 and 48, the protein of Isogai is considered to be a fragment of the undefined/unspecified polypeptide of claim 37. With respect to claim 46, the protein of Isogai is considered to be a splice variant of the undefined/unspecified polypeptide of claim 37.

#### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 37, 40, 41, 44, 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isogai (NCBI Database, Accession NO. AK001935, February 22, 2000) in view of Edwards (US Patent No. 6,312,922).

Isogai (2/22/00) teaches an isolated cDNA sequence which encodes human protein product which differs from SEQ ID NO: 13 in that it contains an aspartate at amino acid position 410 in place of a valine. In the absence of evidence to the contrary, given the extensive sequence identity between the protein encoded by the cDNA of Isogai and the protein of SEQ ID NO: 13 (i.e., 99% identity), it is considered to be a property of the protein of Isogai that it binds single-stranded telomeric DNA. It is noted that the protein encoded by the cDNA of Isogai has the same chemical structure (i.e., amino acid sequence) as the polypeptide presently encompassed by the claims. A chemical composition and its properties are inseparable. With respect to claims 47 and 48, the protein encoded by the cDNA of Isogai is considered to be a fragment of the undefined/unspecified polypeptide of claim 37. With respect to claim 46, the protein

encoded by the cDNA of Isogai is considered to be a splice variant of the undefined/unspecified polypeptide of claim 37.

Isogai teaches the cDNA that encodes this protein but does not teach expressing the cDNA to obtain an isolated protein.

However, Edwards teaches cloning cDNAs into vectors, expressing the protein encoded by the cDNA and isolating the protein (see, for example, columns 53-58).

In view of the teachings of Edwards, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have cloned the cDNA of Isogai into a vector and to have expressed and isolated the encoded protein in order to have obtained protein products that could be used to generate antibodies and which could be used to characterize the functional activity of the encoded protein.

6. Claims 37, 40, 41, 44, 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isogai (NCBI Database, Accession NO. AK022580, September 29, 2000) in view of Edwards (US Patent No. 6,312,922).

Isogai teaches an isolated cDNA sequence which encodes human protein product which differs from SEQ ID NO: 13 in that it contains an aspartate at amino acid position 410 in place of a valine. In the absence of evidence to the contrary, given the extensive sequence identity between the protein encoded by the cDNA of Isogai and the protein of SEQ ID NO: 13 (i.e., 99% identity), it is considered to be a property of the protein of Isogai that it binds single-stranded telomeric DNA. It is noted that the protein encoded by the cDNA of Isogai has the same chemical structure (i.e., amino acid sequence) as the polypeptide presently encompassed by the claims. A chemical

composition and its properties are inseparable. With respect to claims 47 and 48, the protein encoded by the cDNA of Isogai is considered to be a fragment of the undefined/unspecified polypeptide of claim 37. With respect to claim 46, the protein encoded by the cDNA of Isogai is considered to be a splice variant of the undefined/unspecified polypeptide of claim 37.

Isogai teaches the cDNA that encodes this protein but does not teach expressing the cDNA to obtain an isolated protein.

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In view of the teachings of Edwards, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have cloned the cDNA of Isogai into a vector and to have expressed and isolated the encoded protein in order to have obtained protein products that could be used to generate antibodies and which could be used to characterize the functional activity of the encoded protein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306 or (703)-872-9307 (after final).

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers  
August 21, 2003

*Carla Myers*  
CARLA J. MYERS  
PRIMARY EXAMINER